EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC., Plaintiff and Counterclaim Defendant, v. AMGEN INC., Defendant and Counterclaim Plaintiff.	C.A. No. 18-00924-CFC

DEFENDANT AMGEN INC.'S SECOND NOTICE OF DEPOSITION OF PLAINTIFFS PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 30(b)(6)

PLEASE TAKE NOTICE that, pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure, counsel for Defendant Amgen Inc. ("Defendant" or "Amgen") will take the deposition by oral examination of Plaintiff Genentech, Inc. ("Genentech") on the topics set forth in the attached Schedule A, through one or more officers, directors, agents, or other persons designated by Plaintiff to testify on its behalf.

The deposition will take place before an officer duly authorized by law to administer oaths, at the office of Cooley LLP, 3175 Hanover St, Palo Alto, CA 94304, on a date or dates to be determined as mutually convenient for both parties. The testimony will be recorded stenographically and by videotape. The deposition will be taken for the purposes of discovery and all other purposes permitted by the Federal Rules of Civil Procedure.

47. Facts and data in Your possession regarding the business and financial terms on which You have granted a license to Amgen to any patent.

48. Facts and data in Your possession regarding analyses You have performed regarding the business and financial terms on which You have considered authorizing any third-party to manufacture or sell an authorized biosimilar of any product of Yours.

49. All drivers of consumer demand for Herceptin.

50. Your statements in any filing in any governmental regulatory agency, court, or administrative agency proceeding, including in any inter partes review proceedings, regarding the drivers of consumer demand for Herceptin.

51. Your statements in any filing in any governmental regulatory agency, court, or administrative agency proceeding, including in any inter partes review proceedings, regarding the drivers of commercial success of Herceptin.

52. The commercial value to Genentech You ascribe to each of the inventions claimed in each asserted claim of each Patent-in-Suit.

53. Facts and data in Your possession concerning market demand for the use of air sparging to prevent the reduction of disulfide bonds as claimed in the asserted claims of the ’869 patent.

54. Facts and data in Your possession relating to or reflecting market demand for the dosing regimens claimed in the asserted claims of the ’196, ’379, and ’811 patents.

55. Facts and data in Your possession regarding the significance of a patient’s HER2 positive/overexpressing status as a driver of demand for Herceptin.

56. Facts and data in Your possession regarding the significance of the inventions claimed in the Carter patent as drivers of demand for Herceptin.

57. Facts and data in Your possession regarding the significance of the inventions claimed in the Cabilly Patents as drivers of demand for Herceptin.

58. Facts and data in Your possession regarding the significance of the inventions claimed in the Combination Chemotherapy patents as drivers of demand for Herceptin.

EXHIBIT B

Filed on behalf of Patent Owner Genentech, Inc. by:

David L. Cavanaugh (Reg. No. 36,476)
Robert J. Gunther, Jr. (*Pro Hac Vice*)
Lisa J. Pirozzolo (*Pro Hac Vice*)
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217 Leidesdorff Street
San Francisco, CA 94111

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CELLTRION, INC.,
Petitioner,

v.

GENENTECH, INC.,
Patent Owner.

Case IPR2017-01373
Patent 6,407,213

PATENT OWNER'S RESPONSE

2. Commercial success

Some of Genentech's most successful antibodies embody the '213 claims, including Herceptin®, Perjeta®, Avastin®, Lucentis®, and Xolair®, together generating billions of dollars in revenue annually. (Ex-2029 at 2.) Their success is attributable, in part, to their unique sequences provided using the '213 patent's consensus sequence approach, which allows good binding affinity while minimizing immunogenicity. (Ex-2041 ¶¶263-64.) This commercial success confirms the non-obviousness of the challenged claims. *See Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1379 (Fed. Cir. 2011).

Petitioner argues that Herceptin®'s commercial success is irrelevant because Herceptin® is supposedly not commensurate with the full scope of the claims—for example, because Herceptin does not contain every framework substitution in the *Markush* groups of independent claims 1, 30, 62, and 63. (Paper 2 at 60.) But there is clearly a nexus to at least claims 12, 42, 60, 65, 71, 73-74, and 79, which only recite framework substitutions contained in Herceptin.® (*Supra* p. 31.) A nexus between Herceptin®'s commercial success and at least those claims is therefore presumed. *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000). That the claims may encompass other antibodies does not diminish the nexus between Herceptin® and the claim

limitations, given that Herceptin® is both an embodiment of the claims and coextensive with the claimed features.

I. *Inter Partes* Review Is Unconstitutional.

The Board should terminate this proceeding because it violates Patent Owner's constitutional rights. Patent validity must be litigated in an Article-III court, not before an executive agency. *McCormick Harvesting Mach. Co. v. C. Aultman & Co.*, 169 U.S. 606, 609 (1898). Adversarial patent challenges—like *inter partes* reviews—are also "suits at common law" for which the Seventh Amendment guarantees a jury trial. U.S. Const. amend. VII; *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 377 (1996). Moreover, even if *inter partes* reviews are constitutional in other circumstances, it is unconstitutional for pre-AIA patents—like the '213 patent.

Patent Owner presents this constitutional challenge to preserve the issue pending the Supreme Court's decision in *Oil States Energy Services, LLC v. Greene's Energy Group, LLC*, No. 16-712.

IX. CONCLUSION

The Board should confirm the patentability of claims 4, 12, 30-31, 33, 42, 60, 62-67, 69, and 71-79.

EXHIBIT C

Filed on behalf of Patent Owner Genentech, Inc. by:

David L. Cavanaugh (Reg. No. 36,476)
Rebecca A. Whitfield (Reg. No. 73,756)
Robert J. Gunther, Jr. (*Pro Hac Vice*)
Lisa J. Pirozzolo (*Pro Hac Vice*)
Kevin S. Prussia (*Pro Hac Vice*)
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HOSPIRA, INC.,
Petitioner,

v.

GENENTECH, INC.,
Patent Owner.

Case IPR2017-00731
Patent No. 7,846,441

PATENT OWNER'S RESPONSE

the non-obviousness of the challenged claims. *In re Soni*, 54 F.3d at 750.[16] (Ex-2062 ¶214.)

Fourth, the '441 invention has been an enormous commercial success. Herceptin® is the commercial embodiment of the '441 invention and one of the most successful drugs of all time. There is a direct nexus between Herceptin®'s commercial success and the '441 invention. From 1998 until 2006, the ***only*** approved first-line use of Herceptin® was in combination with a taxoid, as claimed in the '441 patent. (Ex-2012 at 1.) Following its launch, Herceptin® was quickly adopted, resulting in hundreds of millions of dollars in sales in those years immediately following its approval. (Ex-2035 at 17.) Where, as here, the commercial product embodies the claimed invention, a nexus is presumed. *Brown & Williamson Tobacco Corp. v. Philip Morris, Inc*., 229 F.3d 1120, 1130 (Fed. Cir. 2000). Petitioner has not even addressed the nexus between the '441 invention

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[16] Petitioner also argues that the unexpected results for the combination of rhuMAb HER2 with paclitaxel lack a nexus to the challenged claims, which encompass combinations with "any 'taxoid.'" (Paper-1 at 62.) But Petitioner has not offered any evidence that paclitaxel is not representative of taxoids generally. Moreover, Petitioner's nexus argument does not apply to at least claim 8, which is limited to combinations with paclitaxel.

and Herceptin® for purposes of commercial success, let alone rebutted the presumption of a nexus. (Paper-1 at 62.)

2. Petitioner's "simultaneous invention" argument is legally flawed because it rests on the inventor's own work.

Petitioner argues that Baselga '97 demonstrates "near-simultaneous invention of the Challenged Claims." (Paper-1 at 62.) But simultaneous invention is only relevant if it involves individuals working ***independently*** from the inventor. *Trustees of Columbia Univ. v. Illumina, Inc.*, 620 F. App'x 916, 930 (Fed. Cir. 2015). Baselga '97 involves no such independent work; it describes the amended Phase-III-study protocol that the inventor of the '441 patent proposed. (*Compare* Ex-1006 at 10, *with* Ex-2011 ¶¶29-36 & Ex-2007.) Indeed, Petitioner expressly relies on Dr. Hellmann's own work to demonstrate "simultaneous invention." (Paper-1 at 62-63 ("POSITAs like Drs. Baselga, Pegram, and Hellmann turned to the most obvious targets: combinations of known therapies seeking synergistic effects.").)

3. Petitioner's criticisms of Dr. Sliwkowski's declaration lack merit and do not cure the deficiencies in Petitioner's obviousness theory.

During prosecution, Genentech submitted the declaration of Dr. Mark Sliwkowski. His declaration explained that a POSA would not have had a reasonable expectation of success in achieving the '441 invention based upon what

EXHIBIT D

CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC., Plaintiff, v. AMGEN INC., Defendant and Counterclaim Plaintiff.	Case No. 1:18-cv-00924-CFC

PLAINTIFF GENENTECH, INC'S RESPONSES AND OBJECTIONS TO DEFENDANT AMGEN, INC.'S SECOND RULE 30(b)(6) DEPOSITION NOTICE

Pursuant to Rules 26 and 30 of the Federal Rules of Civil Procedure and the Local Civil Rules of the United States District Court for the District of Delaware, Plaintiff Genentech, Inc. ("Genentech") hereby objects and responds to the Second Notice of Deposition Pursuant to Rule 30(b)(6) dated November 27, 2019 (the "Notice") served by Defendant Amgen, Inc. ("Amgen").

GENERAL OBJECTIONS

Plaintiff incorporates each of the following General Objections into its responses to each of the Topics for Examination ("Topics"), whether or not each such General Objection is expressly referred to in a response to a specific Topic.

1. Genentech objects to the Notice, and to the Definitions and Topics contained therein, to the extent they seek to impose a burden on Genentech greater than or inconsistent with that required by the Federal Rules of Civil Procedure, including Rule 30(b)(6), the Local Rules, or any other relevant rule, statute, regulation, or precedent.

2. Genentech objects to Amgen's definitions of "Plaintiff," "You," and "Your" as overbroad, unduly burdensome, and vague to the extent they purport to place the burden on

TOPIC 50:

> Your statements in any filing in any governmental regulatory agency, court, or administrative agency proceeding, including in any inter partes review proceedings, regarding the drivers of consumer demand for Herceptin.

RESPONSE TO TOPIC 50:

Genentech objects to this Topic to the extent that it fails to describe with reasonable particularity the matters on which examination is requested, and is unduly burdensome and overly broad. Genentech objects to this Topic to the extent that it seeks information that is not relevant to the claims or defenses of any party to this litigation, not reasonably calculated to lead to the discovery of admissible evidence, or seeks discovery that is not proportional to the needs of the case.

Genentech further objects to this Topic because any such filings speak for themselves; accordingly, the information sought by this Topic is more appropriately obtained through other means of discovery.

Based on the foregoing General and Specific Objections, Genentech will not designate a witness to testify regarding this Topic.

TOPIC 51:

> Your statements in any filing in any governmental regulatory agency, court, or administrative agency proceeding, including in any inter partes review proceedings, regarding the drivers of commercial success of Herceptin.

RESPONSE TO TOPIC 51:

Genentech objects to this Topic to the extent that it fails to describe with reasonable particularity the matters on which examination is requested, and is unduly burdensome and overly broad. Genentech objects to this Topic to the extent that it seeks information that is not relevant to the claims or defenses of any party to this litigation, not reasonably calculated to lead to the discovery of admissible evidence, or seeks discovery that is not proportional to the needs of the case.

Genentech further objects to this Topic because any such filings speak for themselves; accordingly, the information sought by this Topic is more appropriately obtained through other means of discovery.

Based on the foregoing General and Specific Objections, Genentech will not designate a witness to testify regarding this Topic.

EXHIBIT E

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC., Plaintiff, v. AMGEN INC., Defendant and Counterclaim Plaintiff.	Case No. 1:18-cv-00924-CFC

PLAINTIFF GENENTECH, INC'S AMENDED RESPONSES AND OBJECTIONS TO DEFENDANT AMGEN, INC.'S SECOND RULE 30(b)(6) DEPOSITION NOTICE

Pursuant to Rules 26 and 30 of the Federal Rules of Civil Procedure and the Local Civil Rules of the United States District Court for the District of Delaware, Plaintiff Genentech, Inc. ("Genentech") hereby amends its objections and responses to the Second Notice of Deposition Pursuant to Rule 30(b)(6) dated November 27, 2019 (the "Notice") served by Defendant Amgen, Inc. ("Amgen").

GENERAL OBJECTIONS

Plaintiff incorporates each of the following General Objections into its responses to each of the Topics for Examination ("Topics"), whether or not each such General Objection is expressly referred to in a response to a specific Topic.

1. Genentech objects to the Notice, and to the Definitions and Topics contained therein, to the extent they seek to impose a burden on Genentech greater than or inconsistent with that required by the Federal Rules of Civil Procedure, including Rule 30(b)(6), the Local Rules, or any other relevant rule, statute, regulation, or precedent.

TOPIC 50:

> Your statements in any filing in any governmental regulatory agency, court, or administrative agency proceeding, including in any inter partes review proceedings, regarding the drivers of consumer demand for Herceptin.

RESPONSE TO TOPIC 50:

Genentech objects to this Topic to the extent that it fails to describe with reasonable particularity the matters on which examination is requested, and is unduly burdensome and overly broad. Genentech objects to this Topic to the extent that it seeks information that is not relevant to the claims or defenses of any party to this litigation, not reasonably calculated to lead to the discovery of admissible evidence, or seeks discovery that is not proportional to the needs of the case.

Genentech further objects to this Topic because any such filings speak for themselves; accordingly, the information sought by this Topic is more appropriately obtained through other means of discovery.

Based on the foregoing General and Specific Objections, Genentech will not designate a witness to testify regarding this Topic.

TOPIC 51:

> Your statements in any filing in any governmental regulatory agency, court, or administrative agency proceeding, including in any inter partes review proceedings, regarding the drivers of commercial success of Herceptin.

RESPONSE TO TOPIC 51:

Genentech objects to this Topic to the extent that it fails to describe with reasonable particularity the matters on which examination is requested, and is unduly burdensome and overly broad. Genentech objects to this Topic to the extent that it seeks information that is not relevant to the claims or defenses of any party to this litigation, not reasonably calculated to lead to the discovery of admissible evidence, or seeks discovery that is not proportional to the needs of the case.

Genentech further objects to this Topic because any such filings speak for themselves; accordingly, the information sought by this Topic is more appropriately obtained through other means of discovery.

Based on the foregoing General and Specific Objections, Genentech will not designate a witness to testify regarding this Topic.

EXHIBIT F

REDACTED IN ITS ENTIRETY

EXHIBIT G

REDACTED IN ITS ENTIRETY

EXHIBIT H

DurieTangri

Eric Wiener
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CONFIDENTIAL

January 28, 2020

Orion Armon
Eamonn Gardner
Michelle Rhyu
Susan Krumplitsch
Daniel J. Knauss
Benjamin Lin
Lauren Krickl

COOLEY LLP

Re: *Genentech, Inc. v. Amgen Inc.* – Case No. 1:18-cv-00924-CFC – Amgen's Document Production

Orion:

I write regarding the remaining depositions in this matter.

I. Amgen's Witnesses

Given that the damages discovery period closes this Friday, Genentech objects to Amgen offering three of its witnesses only after that date. This is prejudicial to Genentech because Genentech's expert reports are due February 14. Amgen has known topics on which these witnesses are testifying since late November, thus this tactic appears to be an attempt to squeeze Genentech given its impending damages expert report due date. Genentech will not object to the timing of these depositions if Amgen consents to Genentech serving its expert reports on February 17, 2020 (with no other modifications to the pre-trial schedule based on this accommodation). Please let me know if Amgen consents to this proposal.

With respect to the specific dates offered, Genentech will proceed with Mr. Stefureak's deposition this Friday, January 31, Mr. Jones's deposition next Monday, February 3, Mr. D'Inca's deposition next Tuesday, February 4, and Mr. Wong's deposition next Thursday, February 6. Please advise of Mr. Dionne's availability as soon as possible.

II. Genentech's 30(b)(6) Witness Designations

A. Topic 8

In its January 19 Amended Objections and Responses to Amgen's Second Rule 30(b)(6) Notice, Genentech designated Gina Chapman to testify regarding this topic. Your provision of the specific statements the night before that deposition was insufficient to specifically prepare her on those statements, however you had the opportunity to ask her about them. Accordingly, Genentech will not provide further 30(b)(6) testimony on this topic.

B. Topics 50 and 51

In my previous letter I stated that Genentech would further consider the propriety of these topics if Amgen identifies the specific statements about which it seeks testimony. You failed to do so. In any event, Genentech already prepared and offered a 30(b)(6) witness to testify regarding the drivers for demand for Herceptin (Melissa Abreu), and you questioned her extensively about this topic. To the extent the statements within the scope of these topics related to the demand for Herceptin, you could have asked Ms. Abreu about them. Genentech will not provide further 30(b)(6) testimony on this topic.

C. Topic 64

Genentech has already provided testimony regarding the market acceptability of the alleged non-infringing alternatives to the claimed dosing regimens of the patents-in-suit identified in Amgen's interrogatory responses in relation to Topic 65, and thus will not provide additional testimony on this topic with respect to the dosing patents. With respect to the Kao patent, the non-infringing alternatives Amgen identified in its interrogatory responses contain Amgen Confidential information and relate to Amgen's manufacturing processes; Genentech cannot provide fact witness testimony addressing alternatives to Amgen's confidential manufacturing process. Additionally, Genentech has stated that it does not intend to present Genentech fact witness testimony regarding the cost of implementation of any of Amgen's alleged non-infringing alternatives. Accordingly, Genentech will not provide further 30(b)(6) testimony on this topic.

D. Topic 68

We are unaware of any "comparative analyses" of the sort described in your January 23 letter, and therefore there is no 30(b)(6) testimony to provide. I note that in my previous letter I requested that Amgen identify any specific "comparative analyses" on which it seeks testimony beyond those encompassed by Genentech's existing designations or by the testimony Genentech has already provided regarding, e.g., clinical trials relating to the dosing patents, and that Amgen has not done so.

E. Topics 35-38 and 43

Before your January 24 email, Amgen never suggested that the parties' discussion regarding potentially foregoing 30(b)(6) testimony on licensing-related topics would exclude Genentech's licensing of the patents-in-suit to the other biosimilar manufacturers. Indeed, it was Amgen that proposed that the parties forego such testimony because of the limitations both sides had placed in their objections to the topics, for example limiting the scope of the topics to the terms of the agreements. There was never any distinction made between licenses to the patents-in-suit or other licenses, including when Mr. Liss discussed this issue with you on January 25 during the Mel Abreu deposition.

Additionally, your last-minute alteration of the agreement came just 20 minutes before Gina Chapman, the witness whom Genentech had previously designated on the topics in question, was to be deposed. Based on our understanding of the agreement (which I outlined in my January 23 email), we did not prepare Ms. Chapman to testify on behalf of Genentech on these topics. Indeed, the letter you sent on January 23, following my email on the licensing topics, included a section entitled "Genentech's 30(b)(6) Witness Designations," and made no mention of the licensing-related topics. It would be unfair and prejudicial to Genentech to require it to prepare a witness on these topics at this point, given that its chosen designee has already been deposed, and given the impending close of fact discovery, which is just days away.

Genentech further objects to providing 30(b)(6) testimony on Topic 38, which concerns Genentech's policies for licensing patents (even limited to the Settlement Agreements as you January 24 email suggested). This is precisely the type of testimony we discussed mutually foregoing as it implicates primarily privileged issues with respect to the Settlement Agreements.

***

In an attempt to reach a resolution on all of these issues, Genentech is willing to offer a 30(b)(6) witness on topics 35-37 as they pertain to the Settlement Agreements Genentech entered into with Mylan, Pfizer, Celltrion/Teva, and Samsung/Merck relating to those companies' Herceptin biosimilar products as long as Amgen agrees not to seek further testimony on the remainder of the topics identified in this letter. Please provide your position on this as soon as possible so Genentech can identify a witness. Amgen would also have to consent to taking this witness after the close of fact discovery (next week); however given Amgen's proposed dates for its own witnesses, I expect you will have no objection to that timing.

Sincerely,

Eric Wiener

CC: Counsel of Record

EXHIBIT I

REDACTED IN ITS ENTIRETY